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510(K) SUMMARY
UD-1000 A/B Scanner

This 510(K) summary of safety and effectiveness for the UD-1000 A/B Scanner is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(K) summary.

Applicant:	Tomey Corporation USA
Address:	300 Second Avenue Waltham, MA 02451
Contact Person:	Rick Mahoney Director of Business Development
Telephone:	781-890-1515 781-290-5885 (fax)
Preparation Date: (of the Summary)	January, 2002
Device Name:	UD-1000 A/B Scanner
Common Name:	Biometer
Classification Name:	System, Imaging, Pulsed Echo, Ultrasonic (see: 21 CFR 892.1560). Product Code: IYO. Panel: 90.
Legally marketed predicate devices:	Biophysic Medical Ophthascan B (K844686), Nidek US-3000 (K882162), Humphrey Instruments, Inc. Ophthalmic A/B Scan System Model 835 (K923348/A), and Paradigm Medical Industries, Inc. UBM Plus Model P45 (K003141).
Description of the Device:	This instrument is designed as an ophthalmic diagnostic instrument that performs both A-mode and B-mode ultrasound. In B-mode, the instrument acquires an ultrasonic cross-sectional image of echoes from ocular structures. The brightness of the various dots in the two-dimensional image depends on the intensity of the echo sources. In A-mode, the instrument provides a one-dimensional display of returning echoes. Positive waves indicate the location of ocular structures; the distances between spikes can be measured.

The B-scan probe transmits focused ultrasonic waves into the eyeball. The transducer oscillates back and forth, resulting in a two-dimensional cross-sectional image view of the ocular structures. The image represents a "slice" through the portion of eye that is being examined. The ultrasonic beam focus range is controlled by six annular oscillators that are arranged concentrically. Multiple images can be saved and played back at the most appropriate resolution.

The B-scan probe is used to indirectly measure axial length based on a linear sampling of the image of the eye. Although this measurement is less accurate than axial length measurement by A-scan biometry, it provides a useful approximation in patients unable to maintain a steady primary gaze or in eyes with dense cataract, detached retina or posterior staphyloma.

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The A-scan probe emits a non-focused ultrasound beam that results in a one-dimensional representation of echoes returned from ocular structures through which the beam passes. Ocular abnormalitites may be identified and evaluated by assessing the location and amplitude of the spikes produced by various ocular tissues.

The instrument control panel is a touch panel with membrane switch, rotary encoder and foot switch.

Indications for Use:

The UD-1000 A/B Scanner is indicated for:

- Ultrasound imaging of the eye and orbit
- Producing axial measurements of the eye
- Imaging the intraocular anatomy and pathology of the eye
- Imaging the anterior segment of the eye
- Imaging the anterior angle for Glaucoma Management
- Imaging of other structures of the anterior chamber

Comparison to Claimed Predicates: The specifications of the UD-1000 A/B Scanner are the same or very similar to those of the claimed predicates.

Performance Data: None. The specifications and indications for use of the UD-1000 A/B Scanner are the same or very similar to those of the claimed predicate devices. The UD-1000 has the same indications for use for which the claimed predicates have been cleared and has no additional indications for use.

Because of this, performance data were not required.

Conclusion: Based on the foregoing, Tomey believes that the UD-1000 A/B Scanner is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2002

Tomey Corporation USA
% Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
NORTH READING MA 01864

Re: K020151
Trade Name: UD-1000 Ultrasonic A/B Scanner Ophthalmic Biometer
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Dated: January 11, 2002
Received: January 16, 2002

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the UD-1000 Ultrasonic A/B Scanner Ophthalmic Biometer, as described in your premarket notification:

Transducer Model Number

B-Scan 10 MHz
A-Scan 10 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Joseph Arnaudo at (301) 594-1212.

Sincerely yours,

David G. Segerson

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

system

Diagnostic Ultrasound Indications for Use Form

System:UD-1000 **Transducer:**____________

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other (specify)
Ophthalmic	**N**	**N**								
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:____________

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[✓ Prescription Use (Per 21 CFR 801.109)]

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020151

Diagnostic Ultrasound Indications for Use Form

System:____________________ **Transducer:** **B-Scan 10 MHz**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other (specify)
Ophthalmic		**N**								
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[✓ Prescription Use (Per 21 CFR 801.109)]

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020151

Diagnostic Ultrasound Indications for Use Form

System:________________ **Transducer:** A-Scan 10 MHz ✓

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other (specify)
Ophthalmic	**N**									
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

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